K103523

Special 510(k): Device Modification
185A+ Incubator with PulseOx
November 22, 2010

MAY 1 1 2011

510(k) SUMMARY

Submitter Information:

International Biomedical
8508 Cross Park Drive
Austin, TX 78754
U.S.A.

Regulatory Affairs Contact:

Amy Pieper
Director of Regulatory Affairs
(512) 873-0033 - phone
(512) 873-9090 - fax

Date Summary Prepared:

November 22, 2010

Device Identification:

Trade Name: 185A+ Transport Incubator with PulseOx
Common Name: Transport Incubator
Classification Name: Neonatal Transport Incubator (FPL)

Predicate Device:

Transport Incubator 185A Incubator (k031096)

Intended Use:

The transport incubator is a neonatal transport incubator. The incubator circulates warmed air at an operator selected, controlled temperature into a transparent chamber containing an infant. The structural integrity and weight of the incubator makes it suitable for ground and air transport. Auxiliary equipment for airway management and vital signs monitoring are not standard equipment. The system is to be operated by trained medical technical personnel.

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Functional Description and Technological Characteristics:

The 185A+ Transport Incubator with PulseOx (hereafter referred to as the transport incubator) maintains a thermally regulated environment to prevent infant heat loss when transporting neonatal infants to hospitals prepared for neonatal infant care. The transport incubator maintains a thermally regulated environment with either externally supplied power or internal power supplied by a rechargeable battery. The transport incubator is also designed to offer integrated pulse oximetry and oxygen monitoring capability on the display panel. The transport incubator is also designed to carry equipment designed for life support and monitoring of the neonatal infant's status. The equipment includes but is not restricted to: hand and mechanical operated ventilator's; ventilator monitors; infusion pumps; patient monitors indicating blood pressure, respiration, electrocardiogram, oxygen saturation, pulse, etc.; suction pumps; oxygen analyzers; air and oxygen cylinders; air compressors; etc.

The integrated pulse oximeter feature is designed to use either Nellcor or Masimo technology. The Nellcor PulseOx model utilizes a daughter board and patient cabling provided by Nellcor. The Masimo PulseOx model utilizes a daughter board and patient cabling provided by Masimo.

Substantial Equivalence:

In summary, the 185A+ Transport Incubator with PulseOx described in this submission are, in our opinion, substantially equivalent to the predicate device, in regards to intended use and safety and effectiveness.

Performance Testing:

Performance testing of the 185A+ Transport Incubator with PulseOx has been conducted for functional and design verification and validation. The testing indicates the incubator is in compliance with the following recognized consensus standards:

- IEC 60601-1 Medical Electrical Equipment, Part 1 : General Requirements for Safety
- IEC 60601-1-2 Medical Electrical Equipment, Part 1: General Requirements for Safety, Electromagnetic Compatibility-Requirements and Tests
- IEC 60601-2-20 Medical Electrical Equipment, Part 2: Particular Requirements for Safety of Transport Incubators
- ISO 9919 Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use
- ISO 21647 Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Amy Pieper
Director of Regulatory Affairs
International Biomedical, Limited
8508 Cross Park Drive
Austin, Texas 78754

MAY 1 1 2011

Re: K103523
Trade/Device Name: 185A+ Transport Incubator with PulseOx
Regulation Number: 21 CFR 880.5410
Regulation Name: Neonatal Transport Incubator
Regulatory Class: II
Product Code: FPL
Dated: April 12, 2011
Received: April 14, 2011

Dear Ms. Pieper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k):
185A+ Transport Incubator with PulseOx
November 22, 2010

INDICATIONS FOR USE

510(k) Number (if known): K103523

Device Name: 185A+ Transport Incubator with PulseOx

Indications For Use:

The transport incubator is a neonatal transport incubator. The incubator circulates warmed air at an operator selected, controlled temperature into a transparent chamber containing an infant. The structural integrity and weight of the incubator makes it suitable for ground and air transport. Auxiliary equipment for airway management and vital signs monitoring are not standard equipment. The system is to be operated by trained medical technical personnel.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/11/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103523